

Application No.: 10/017721

Response dated August 19, 2003

Reply to Restriction Requirement dated June 19, 2003

Group Art Unit: 1631

Remarks and response to Restriction Requirement begins on page 3 of this paper

REMARKS

Election/Restriction

The Examiner has required restriction to one of the following inventions under 35 U.S.C. § 121:

- I. Claims 1-7, drawn to a method for identifying a subject as a candidate for a particular clinical course of therapy to treat a vascular disease or disorder, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE the below summarized specie elections and additional subspecie elections are also required.
- II. Claims 8-12, 40-43, and 49-62, drawn to a method for diagnosis and for identifying a subject who is a candidate for further diagnostic evaluation for a vascular disease or disorder, classified in class 706, subclass 21 and 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then THREE of the below summarized specie elections are also required.
- III. Claims 13-19, 47, and 48, drawn to a method of treating and for selecting a clinical course of therapy to treat a subject who is at risk for developing a vascular disease or disorder, classified in class 435, subclass 6 and class 514, subclass 1. If this Group is elected then the below summarized sequence elections are also required. Also, if this Group is elected then ONE of the below summarized specie elections and additional subspecie elections are also required.
- IV. Claims 20-21, drawn to a method for determining if a subject will benefit from a stent implantation, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.
- V. Claims 22-24, drawn to a method for determining if a subject will benefit from a vascular imaging procedure, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.
- VI. Claims 25-27, drawn to a method for determining if a subject will benefit from a surgical procedure, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie elections is also required.

VII. Claims 28-30, drawn to a method for selecting an effective vascular imaging device as a diagnostic tool, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.

VIII. Claims 31-39, drawn to a computer readable medium, electronic system, and network system used in performing a method of predisposition determination to a vascular disease or disorder, classified in class 211, subclass 41.12; class 702, subclass 19; and class 706, subclass 21. If this Group is elected then the below summarized sequence election is also required.

IX. Claims 44-46, drawn to a method for selecting the appropriate drug for a vascular disease or disorder, classified in class 702, subclass 27. If this Group is elected then the below summarized sequence election is also required.

X. Claims 63-67, drawn to a nucleic acid and kit comprising an allelic variant of a polymorphic region, classified in class 536, subclass 23.1. If this Group is elected then the below summarized sequence election is also required.

XI. Claims 68-88, drawn to a method and medical information system of determining identity of one or more allelic variants of a polymorphic region, classified in class 706, subclass 21 and class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie elections is also required.

XII. Claims 89-93, drawn to a computerized method of providing medical advice, classified in class 706, subclass 46. If this Group is elected then the below summarized sequence election is also required.

XIII. Claims 94-104, drawn to a method for self-assessing risk for a vascular disease, classified in class 706, subclass 45. If this Group is elected then the below summarized sequence election is also required.

XIV. Claims 105-106, drawn to a method for health care provider to generate a personal health assessment report, classified in class 706, subclass 45. If this Group is elected then the below summarized sequence election is also required.

XV. Claims 107-134, drawn to a method for assessing the health of an individual using digital molecular and digital health data in its assessment determination, classified in class 706, subclass 47. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie elections is required.

Application No.: 10/017721
Response dated August 19, 2003
Reply to Restriction Requirement dated June 19, 2003

Group Art Unit: 1631

Applicants hereby elect, without traverse, **Group II** (claims 8-21, 40-43, and 49-62) under 35 U.S.C. §121 for prosecution in the present application. Applicants reserve the right to traverse the above restriction with respect to non-elected Groups I and II-XV in this or subsequent applications.

In addition, the Examiner has required that if Group II is elected, a “sequence election” is also required. With respect to the Sequence Election, the Examiner is of the opinion that

[t]he claims in this invention read on patentably distinct sequences. For nucleotide sequences, the Applicants must elect a single nucleic acid sequence with one nucleotide position therein, or alternatively, a specific set of sequence and/or nucleotide positions within each elected sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement. MPEP 803.04 states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement.

It is Applicants' understanding that the Sequence Election requirement as set forth above requires that Applicants elect one sequence from SEQ ID NO:1 and SEQ ID NO:3. Accordingly, Applicants hereby elect SEQ ID NO:1, *with traverse*.

Applicants traverse the Sequence Election requirement for the following reasons. The elected claims are directed to the use of one or more specific polymorphisms within SEQ ID NO:1, either alone, *or in combination with*, one or more specific polymorphisms within SEQ

ID NO:3. Accordingly, Applicants respectfully submit that the claimed invention may include methods for use of polymorphism(s) within SEQ ID NO:1, polymorphism(s) within SEQ ID NO:3, or polymorphisms from both SEQ ID NO:1 and SEQ ID NO:3. Therefore, Applicants respectfully submit that in order for the complete invention to be included within the search, both SEQ ID NO:1 and SEQ ID NO:3 should be searched.

Furthermore, the Examiner states that, if Group II is elected, "then THREE of the below summarized specie elections are also required." The Examiner further states that Applicants are required to "elect a single disclosed specie or subspecie for the appropriate specie and subspecie elections for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable."

Applicants respectfully traverse the species election. Applicants respectfully submit that a search for the claimed methods will necessarily include any further diagnostic evaluation, including vascular imaging devices, any vascular disease, and diagnosis for increased or decreased likelihood of disease, and therefore will be co-extensive.

However, to be considered responsive to the instant Restriction Requirement, Applicants elect under 35 U.S.C. §121, *with traverse*: L (a vascular imaging device which is angiography); W (a vascular disease which is coronary artery disease); and MM (a method of diagnosis of increased likelihood of disease), as the species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 8, 40 and 49 are readable on these species. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

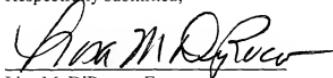
Application No.: 10/017721
Response dated August 19, 2003
Reply to Restriction Requirement dated June 19, 2003

Group Art Unit: 1631

CONCLUSION

It is respectfully submitted that this application is in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,



Lisa M. DiRocco, Esq.
Registration No. 51,619
for
DeAnn F. Smith, Esq.
Registration No. 36,683
Attorney for Applicants

28 State Street
Boston, MA 02109
Telephone: (617) 227-7400
Facsimile: (617) 742-4214

Date: August 19, 2003